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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,682	03/17/2004	Akira Asakura	13735 US1 (C038435/010970)	9826
7590 Stephen M. Haracz, Esq. BRYAN CAVE LLP 1290 Avenue of the Americas New York, NY 10104-3300			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/802,682

Applicant(s)

ASAKURA ET AL.

Examiner

Malgorzata A. Walicka

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on Jan. 16, 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 9.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 2, 3, 20, -22 25, and 28-31.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☒ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

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Please disregard final action mailed in error on Feb. 20, 2007. The correct action is herein.

The examiner acknowledges the Amendment after final rejection filed Jan 16, 2007 comprising the amendment's to the claims, REMARKS and exhibits Presenting pages 9.47-9.58 of Sambrook et al., Molecular Cloning (2nd ed.), Cold Spring Harbor Laboratory Press 1989, New York are acknowledged.

Claims 1, 2, 30 and 31 have been amended. Claims 4-8, 10-19, 23-24 and 26-27 were previously canceled. Claims 1-3, 9, 20-22, 25, 28-31 are pending.

ADVISORY ACTION

Claims 1, 2, 3, 20-22, 25 and 29-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "hybridizes under stringent conditions" and "stringent washing conditions" which being indefinite, renders the claim indefinite. There are many sets of hybridization conditions in the prior art that are used for identifying DNA molecules by hybridization, and the choice of a particular set depends on the experimenter and the experimental problem at hand. Different hybridization conditions lead to different selection of DNA molecules. The claims do not explicitly state the conditions which Applicants call "stringent".

Response to Applicants arguments

Applicants in their current REMARKS (page 6, the last line) argue,

"The specification as filed provides details as to how this phrase [stringent hybridization and stringent washing conditions] is to be interpreted, see, e.g. page 16, lines 9-15. For exact details of these hybridization procedures, the specification cites Sambrook et al., Molecular Cloning (2nd ed.), Cold Spring Harbor Laboratory Press 1989, New York. For example Sambrook provides on page 9.52 a complete proteocol for stringent hybridization and stringent washing conditions. A copy of this protocol is attached as Exhibit 1."

Applicants' argument has been fully considered but is found not persuasive for the following reasons.

I. The specification as filed does not provide details as to how this phrase is to be interpreted. Page 16, lines 9-15 of the specification read as follows:

"Standard conditions' for hybridization mean in this context the conditions which are generally used by one skilled in the art to detect specific hybridization signals and which are described, e.g. by Sambrook et al., 'Molecular Cloning' second edition, Cold Spring Harbor Laboratory Press 1989, New York. Such 'standard conditions' are preferably, stringent hybridization and non-stringent washing conditions, or more preferably stringent hybridization and stringent washing conditions **familiar to those skilled** in the art and which are described, **e.g.,** in Sambrook et al [emphasize added] ."

One having skilled in the art realizes that the quoted passage of the specification does not provide details for stringent hybridization and stringent washing conditions

because the phrase "familiar to those skilled in the art" is indefinite since there are many sets of stringent hybridization and stringent washing conditions, and what is "familiar" for one experimenter is not necessarily familiar for the other. Reference to Sambrook et al. is used in exemplary way, thus quoting Sambrook et al. does not exclude conditions other than presented by Sambrook et al.

II. As to page 9.52 of Sambrook et al., page 9.52 even does not contain the phrase "stringent hybridization and stringent washing conditions". It describes prehybridization solutions, "**appropriate for the task at hand**" [emphasis added], which are suitable "**for detection of low-abundance sequences**" or "**for moderate- or high abundance sequences**".

What task have been at Applicant's hand, and have Applicants detected low abundance sequences or moderate-or high abundance sequences? What have been conditions for hybridization and washing?

35 U.S.C. 112 first paragraph

Scope of enablement

Claims 1-3, 20-22, 25, 28, 30-31 are rejected in the previous action because the specification, while being enabling for the alcohol and aldehyde dehydrogenases of SEQ ID NO: 5, 6, 7, and 8, is not enabling for the invention as claimed. The disclosure does not teach the stringent hybridization conditions and stringent washing conditions to be used in selection of DNA molecules of invention, claims 1-3, 20-22, 25, 28, 30-31 as amended are not enabled and thus rejected. In addition, claim 2 and 3 are rejected

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under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the plasmid comprising genes encoding SEQ ID NO: 5 and SEQ ID NO: 8 (plasmids pSSAB201 and pSSBA201), does not reasonably provide enablement for an enzyme that comprises a combination of at least two amino acids sequences each of said sequences being selected from the group of SEQ ID NO: 8 and SEQ ID NO: 5 and amino acid sequences encoded by DNA sequences hybridizing under stringent hybridization conditions and stringent washing conditions DNA molecules according to SEQ ID NO: 4 or 1. The reasons were explained in the previous Office actions.

Response to Applicants' arguments

In their current REMARKS page 8, line 21 Applicants emphasize that Sambrook, on page 9.47 states, that aqueous solutions and solutions of 50% formamide are both solvents that show excellent results, and conclude

"Therefore, the Examiner's statement that 'the disclosure does not teach the hybridization conditions to be used in selection of DNA molecules of [the] invention' in ***misplaced***"; emphasis and bracket are added by Applicants.

Applicants' argument has been fully considered but is found not persuasive.

I. The claims do not quote anywhere a solution containing 50% formamide or aqueous solutions, thus referring to them is not to the point.

II. Sambrook et al. on page 9.47 do not refer to one set of ready to be used stringent hybridization conditions and stringent washing conditions", actually they even do not use the phrase "stringent hybridization conditions and stringent washing

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conditions". What Sambrook et al. do is starting the page with enumerating seven respects in which "many methods available to hybridize" differ. After that Sambrook et al. continue:

"Although the choice depends to a large extent on personal preference [emphasis added], we offer the following guidelines for choosing among the various methods available."


The disclosure is silent as to what was Applicants' personal preference, or which of the various methods available they have chosen.

Conclusion

Claim 9 is allowed for the reasons indicated by the examiner in the First Office Action on merits on Dec. 1, 2004.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-1600. The fax phone number for this Group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 872-9306.

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Patent Examiner
Art Unit 1652


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